

File No. 11014/05/2019-QA (part file)  
**Food Safety and Standards Authority of India**  
(A statutory Authority established under the Food Safety and Standards Act, 2006)  
(Quality Assurance Division)  
**FDA Bhawan, Kotla Road, New Delhi - 110002**

Dated, the 12<sup>th</sup> January, 2021

**Notice**

**Subject: Approval of Rapid Analytical Food Testing (RAFT) Kit/Equipment/ Method by FSSAI- reg.**

This is in suppression of FSSAI notice number 11014/05/2019-QA dated 18.09.2019.

2. The application format for applying to FSSAI for approval of Rapid Analytical Food Testing Kit/Equipment/Method for the purpose of testing of food has been revised.

3. In view of above, the desirous manufacturers/method developers may apply to FSSAI in the revised application format and are hereby requested to follow the below mentioned points while submission of the application-

- (i) Duly filled complete and signed application will only be accepted by FSSAI. Incomplete or unsigned applications will be summarily rejected and no fee shall be refunded.
- (ii) Applicants should submit separate application for each kit/equipment/method and each application should be accompanied by separate application processing fee (@Rs. 2000/- + GST @18% is for approval of a single rapid food testing kit/equipment/method in a single application form).
- (iii) Application should be submitted with proper justification for each of the product separately along with all necessary/ supporting documents (validation certificate in accordance with international guidelines/data and manual/product insert).
- (iv) No application for instruments used for analysis of general parameters like pH, density or routine laboratory equipments and accessories etc. will be accepted. Such applications, if received will be summarily rejected and no fee shall be refunded.
- (v) Any kit capable of detecting a class of antibiotics as per FSSR will be considered by the committee.

4. The duly filled application form (copy enclosed) shall be sent to the undersigned through e-mail (raft-approval@fssai.gov.in) and also by post in 2 sets.

5. The requisite fee structure and the decision-making process for RAFT Application are annexed for kind information.

  
(Dr. Dinesh Kumar)  
Assistant Director (QA)  
Email:raft-approval@fssai.gov.in

To:  
IT Division, FSSAI - for uploading on FSSAI's website

## Brief of the process

<b>Objective</b>	To approve the rapid food testing kits or equipments or method of analysis		
<b>Fees</b>	<p><b>a) Common requirements-</b>            (i) Duly filled application in the prescribed format;            (ii) Application processing fee of Rs. 2,000 + GST @18% (not included in the fees prescribed against each category) per application/product in favour of Sr. Accounts Officer, FSSAI payable at New Delhi by Demand Draft or through online mode (the bank account details of FSSAI are mentioned in application form)</p> <p><b>b) For hand held or portable equipments-</b>            (i) At least 20 instruments – can be taken back by the manufacturer after the trials;            (ii) Details of method / technology on which the equipment is based;            (iii) Validation/scrutiny fee of Rs. 10,000 per laboratory who will undertake process of validation of the test kit/equipment/method.</p> <p><b>c) For test kit(s)-</b>            (i) At least 25 kits with clear details of instruction;            (ii) Details of method/technology on which the kit is based;            (iii) Validation/scrutiny fee of Rs. 25,000 per laboratory who will undertake process of validation of the test kit/equipment/method.</p> <p><b>d) For method(s)/protocols-</b>            (i) Binded copies of methods clearly specifying different steps involved;            (ii) Details of relevant conventional method(s)/protocol(s) for which the rapid method is alternative; and, sources of reference materials;            (iii) Validation/scrutiny fee of Rs. 2.5 to 5.0 lakhs depending on the chemicals involved per laboratory who will undertake process of validation of the test kit/equipment/method.</p> <p><b>e) For issuance of certificate by FSSAI</b>            (i) The manufacturer/method developer shall pay a fee of Rs. 25,000 + GST @18% for the issuance of the Conformance Certificate (CC);            (ii) Subsequent renewal, if recommended by MRG &amp; SPMSA and approved by the competent authority, will attract a renewal fee of Rs. 10,000 + GST @18%.</p>		
<b>Timeline for scrutiny of application</b>	<b>S. No.</b>	<b>Activity</b>	<b>Timeline</b>
	1.	Scrutinization of RAFT application	By the RAFT Secretariat [3 working days from date of receipt of application]
	2.	Desktop audit of technical components of the application and subsequent recommendation to the Sc. Panel on Methods of Sampling & Analysis (SPMSA)	By the RAFT Committee [4-6 weeks]
	3.	Ratification of the recommendation of RAFT Committee by the SPMSA	First available meeting*
	4.	Approval of the recommendation of the SPMSA by the Competent Authority of FSSAI	Immediately after finalization of minutes of the panel meeting
	5.	Issuance of Conformance Certificate	6-7 working days from the date of approval by the Competent Authority subject to deposition of requisite fee by the applicant
	<i>* Usually panel meetings are held once in 3 months</i>		
<b>Validity of Conformance Certificate</b>	The Conformance Certificate will be valid for three years from the date of issue		
<b>Withdrawal of Conformance Certificate</b>	FSSAI may withdraw or suspend the Conformance Certificate issued to applicant on the basis of its own investigation or complaint received in this regard or voluntarily withdrawal request from the applicant		

**APPLICATION FORM FOR APPROVAL OF RAPID ANALYTICAL FOOD TESTING  
(RAFT) KIT/EQUIPMENT/METHOD BY FSSAI**

<p><b>A. Application for (tick whichever is appropriate)</b></p> <p><input type="checkbox"/> Rapid food testing kit/media</p> <p><input type="checkbox"/> Rapid Equipment</p> <p><input type="checkbox"/> Rapid Method</p> <p><input type="checkbox"/> Any other, please specify</p>
<p><b>B. General Information</b></p>
<p><b>1. Details of Applicant</b></p>
<p>(a) Name of Principal manufacturer/ OEM</p>
<p>(b) Name of authorized person/ dealer in India (attach Authorization letter from principal manufacturer)</p>
<p>(c) Mobile No/Phone No</p>
<p>(d) Email (all communication will be through provided email/phone number)</p>
<p>(e) Name of the organization/manufacturer</p>
<p>(f) Address of the organization/registered office</p>
<p>(g) Manufacturing License number in India if any</p>
<p>(h) Name of the Rapid test kit/media/device/method</p>
<p>(i) Proposed regulatory use (specific product testing/analytical method)</p>
<p><b>C. Technical Information - Contents to be submitted with the Dossier for pre-evaluation by FSSA(I)</b></p> <p><b><i>NOTE: The applicant should mark any proprietary information</i></b></p>
<p><b>1. Product Information</b></p>
<p>(a) Market name, product name and product code</p>
<p>(b) Names and corporate addresses of manufacturers</p>
<p>(c) Country of Origin</p>
<p>(d) Address(es) of manufacturing site(s)</p>
<p>(e) Whether approved/verified by regulatory bodies/ organizations</p>
<p>(f) If yes, name of regulatory bodies/organizations and validity of approval</p>
<p>(g) If validated by international bodies (e.g. ISO/AOAC etc.)</p>
<p>(h) If yes, attach documents/certificates/approvals etc.</p>
<p>(i) Bar code scanner, power source, data storage capacity (if applicable)</p>
<p>(j) Evidence that manufacturers have a certified quality management system or Good Manufacturing Practice (GMP) certification; if applicable</p>

<b>2. Provide details of the conventional method/equipment/test kit with which the said product should be compared with</b>
<b>3. Technical Specifications on rapid testing kits/device/method</b> ( <i>this list is only indicative all necessary information to support and strengthen the application must be submitted</i> )
(a) The principle and detailed methodology
(b) Specify Food Category/Matrix as per FSSR for which approval is sought
(c) Test procedure, including the time needed to run the test
(d) Qualitative/ Semi Quantitative/Quantitative
(e) Range and Reporting Units (if applicable)
(f) LOD/LOQ/Detection capability
(g) Sensitivity (wherever applicable)
(h) Specificity (including where the studies were performed to generate these values and 95% confidence intervals with supporting documents)
(i) Reproducibility across multiple test kit lots (e.g. including number of samples, type of food, number of different lots/devices)
(j) Inclusivity/ exclusivity (applicable for microbiology kits/methods/device etc.)
(k) Robustness of the kit/method
(l) Details of inter-laboratory validation of method/multiple users of device
(m) Demonstration of stability throughout the shelf life of the product under recommended storage conditions(not applicable to devices and methods)
(n) If device, warranty period, availability of maintenance service/ spare parts etc
(o) Evidence of satisfactory test performance for kits from users (minimum three) within India
<b>4. Operational characteristics for kits/devices</b>
(a) Number of steps (from starting to results)
(b) Total run time (sample preparation to final result)
(c) Ease of data interpretation
(d) Overall ease of use
(e) Training requirements
(f) Recommended storage conditions
(g) Shelf life of kit
(h) Kit size/Device (hand-held/table top/portable/non-portable)
(i) Image/flow-chart of rapid kit/equipment/method

(i) Minimum quantity of sample required for one analysis								
(j) Number of Individual tests/package								
(k) Required accessories necessary for operation that are not provided								
(l) Availability of Certified Reference Material/Standard Reference Material/Quality Control material provided								
(m) Advantages and disadvantages over the conventional technique/method/device								
(n) Amount and type of waste generated (e.g. chemical/biological hazard)								
(o) Cost/Kit and Cost/Test, cost/device								
<p><b>5. Fee details:</b>  Amount paid (Rs. ....)  Mode of payment (Online or Offline*)  Transaction id/UTR No. with date and bank name &amp; account no. (In case of Online payment)  Name of Bank, IFSC Code, DD No. &amp; date (In case of Offline payment)  Name of the payee (both in case of Online or Offline payment)</p> <p><i>*payment through cheque mode and cash will not be accepted.</i></p> <p>The application processing fee of Rs. 2000/- (Rupees two thousand) + GST @18% can be paid through online mode, in the bank account mentioned below-</p> <table style="margin-left: auto; margin-right: auto;"> <tr> <td>Name:</td> <td>Senior Accounts Officer, FSSAI, New Delhi</td> </tr> <tr> <td>Bank:</td> <td>Bank of Baroda, Nirman Bhawan</td> </tr> <tr> <td>Account No:</td> <td>26030100008653</td> </tr> <tr> <td>IFSC Code:</td> <td>BARB0(Zero)NIRDEL</td> </tr> </table> <p>The GST No. of FSSAI is 07AAAGF0023K1ZV (0 is Zero).</p>	Name:	Senior Accounts Officer, FSSAI, New Delhi	Bank:	Bank of Baroda, Nirman Bhawan	Account No:	26030100008653	IFSC Code:	BARB0(Zero)NIRDEL
Name:	Senior Accounts Officer, FSSAI, New Delhi							
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<b>6. Any additional specific information</b>								

I/ We understand that incomplete submissions, submission not conforming to the prescribed format, and applications containing excessive errors will be summarily rejected. I/ We undertake that requisite material/ content will be submitted to FSSAI as desired in case the pre-evaluation document is approved by FSSAI and FSSAI will provide the applicant with instructions for further action. If the documentation is not approved, FSSAI will notify the applicant with reasons.

Name of the authorized personnel .....

Signature and Stamp.....

Contact details.....

To

Advisor, Quality Assurance Division